

(38) The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration, or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(39) The Secretary of Health and Human Services has redelegated to the Commissioner, of Food and Drugs, under 45 CFR 5b.8 regulations, appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(b) The Chief Counsel of the Food and Drug Administration has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335), section 4 of the Federal Import Milk Act (21 U.S.C. 144), and section 9(b) of the Federal Caustic Poison Act.

#### **§ 5.11 Reservation of authority.**

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary of Health and Human Services (Secretary) reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or

more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

### **Subpart B—General Redelegations of Authority**

#### **§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.**

(a) Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as set forth in these subparts. The Commissioner may continue to exercise all authority delegated in subparts B through L.

(b) The following officials are authorized to perform all of the functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

- (1) Deputy Commissioner;
- (2) Associate Commissioner for Regulatory Affairs;
- (3) Senior Associate Commissioner;
- (4) Senior Associate Commissioner for Management and Systems;
- (5) Senior Associate Commissioner for Policy, Planning, and Legislation; and
- (6) Deputy Commissioner for International and Constituent Relations.

(c)(1) During the absence or disability of the Commissioner or in the event of

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a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

- (i) Deputy Commissioner;
- (ii) Associate Commissioner for Regulatory Affairs; or
- (iii) Senior Associate Commissioner.

(2) These officials may not further redelegate this authority. However, for a planned period of absence, the Commissioner (or someone “acting” on his/her behalf) may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as “acting” or unless not legally permissible.

(e)(1) The Senior Associate Commissioner is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with 5.10(a)(17).

(2) The Senior Associate Commissioner is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

(3) The Senior Associate Commissioner is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended.

(4) The Senior Associate Commissioner is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center.

(5) The Senior Associate Commissioner may not further redelegate these authorities.

(f)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation (SACPPL) and the Associate Commissioner for Policy (ACP) are authorized to perform any of the functions of the Commissioner with respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration. These officials may not further redelegate this authority.

(2) The SACPPL and the ACP are authorized to issue responses to the following matters under part 10 of this chapter as follows and these officials may not further redelegate this authority:

- (i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19 of this chapter;
- (ii) Citizen petitions under § 10.30 of this chapter;
- (iii) Petitions for reconsideration under § 10.33 of this chapter;
- (iv) Petitions for stay under § 10.35 of this chapter; or
- (v) Requests for advisory opinions under § 10.85 of this chapter.

(3) With respect to any matter delegated to the SACPPL and the ACP under this paragraph, the SACPPL and the ACP are authorized to perform the function of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under § 10.206(g) and (h) of this chapter. These officials may not further redelegate this authority.

(4) The SACPPL and the ACP are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The SACPPL and the ACP may further redelegate this authority.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

- (1) Senior Associate Commissioner;
- (2) Deputy Commissioner for International and Constituent Relations;
- (3) Senior Associate Commissioner for Management and Systems; or

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(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions under section 735 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 379h) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These officials may not further redelegate this authority. (See subpart C, §5.108 for the user fee-related re delegation to officials within the Center for Drug Evaluation and Research.)

(2) The Senior Associate Commissioner for Management and Systems and the Director, Office of Financial Management, are authorized to perform the functions of the Commissioner under section 736(d)(1)(c) of the act (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situation where he or she finds that “the fees will exceed the anticipated present and future costs.” These officials may not further redelegate this authority.

(3) The Deputy Commissioner, or in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

(i) The Senior Associate Commissioner for Management and Systems is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

(j) Unless specifically noted, the persons to whom the Commissioner has delegated authority in subparts B through L of this part may not further redelegate that authority.

### §5.21 Emergency functions.

(a) Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his or her region to:

(1) Fully represent the Food and Drug Administration within his or her region in cooperation with the Department of Health and Human Services regional emergency plans, and

(2) Exercise the authority of the Commissioner of Food and Drugs for supervision of and direction to all Food and Drug Administration activities and use of resources within his or her region for continuity and for Federal Emergency Health Service operations.

(b) These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters. These officials may not further redelegate this authority.

### §5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the non-existence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputy Chief Counsels.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).